

K252046 Zoom System (Zoom 4S Catheter)Oct 30, 2025
122 days to decisionK252046 · Product code: **NRY** · Neurology
Source: <https://www.510kdatabase.net/k252046/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Thrombus Retriever (NRY)
Date received	Jun 30, 2025
Decision date	Oct 30, 2025
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Imperative Care, Inc.
Location	Sunnyvale, CA, US
Contact	Peter Taylor
510(k) history	17 submissions · 17 cleared · 2018-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252046/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026